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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 10/030,619   | 10/21/2002  | Kojiro Takahashi     | TAKAHASHI30          | 8322             |
| 1444   | 7590        | 03/23/2004           | EXAMINER             |                  |
| BROWDY AND NEIMARK, P.L.L.C.<br>624 NINTH STREET, NW<br>SUITE 300<br>WASHINGTON, DC 20001-5303 |             |                      | WESSENDORF, TERESA D |                  |
|  |             |                      | ART UNIT             | PAPER NUMBER     |
|  |             |                      | 1639                 |                  |

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/030,619

**Applicant(s)**

TAKAHASHI ET AL.

**Examiner**

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 2/12/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/12/04 has been entered.

#### ***Specification***

The disclosure is objected to because of the following informalities: the specification is still full of grammatical, idiomatic and/or typographical errors too numerous to mention specifically.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 21-24 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility.

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The specification fails to describe a utility for the claimed cDNA or gDNA immobilized library. The disclosure at page 17 simply recites the "possibility of use" of the library. The possibility of use is not a specific utility as required by the law. There is not a single example to demonstrate the possible use of the library.

"Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The court in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility....A patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

Claims 21-24 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled

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in the art clearly would not know how to use the claimed invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The as filed-specification does not provide support for new claim 24. The original disclosure at e.g., page 8, line 14 up to page 10, 27 recites a different concept for a replica support. MPEP 714.02 states that applicants specifically point out where in the specification support for the new claims can be found. [Furthermore, the specification at page 22, lines 7-9 appear to recite essential features of the invention but are not claimed. See also, page 23, lines 13-16].

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***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35

U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. There seems to be no correlation in the steps of the claimed method. For example, the connection of the test material of step(d) to any of the preceding steps a-c. The claimed steps appear to be independent from each other. It recites for different components and unclear as to what is actually being claimed. The claim fails to point out what is included or excluded by the claim language. [Cf. with page 21, last incomplete paragraph up to page 27 first incomplete paragraph.] It is not clear as to the means by which the time or temperature have been "predetermined" especially in view of the lack of said predetermination in the specification. The disclosure recites for example as to the range of said predetermined time and temperature. The term "lower" is a relative term which renders the claim indefinite. The term "lower" is not defined by the

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claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

2. Claim 23 is unclear as to whether the first support is the original support. Step (a) appears to lack a component for the hybridization reaction. [Cf. with page 8, line 12 and page 10, line 27 of the disclosure.] Step (g) is unclear as to how the anti-sense is obtained, especially since the preceding steps do not recite said anti-sense. [Cf. with page 8, line 24 of the method steps in the specification].

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly

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or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Takahishi et al (US PAT.NO. 6,489,111) for reasons of record.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

#### ***Response to Arguments***

Applicants argue that the new claims 21-24 required the use of clearly recited apparatus for feeding solutions and controlling the reaction conditions.

In reply, attention is directed to Takahashi's disclosure at col. 4, line 29 up to col. 5, line 13 which discloses an apparatus for the claimed method of making a cDNA (complementary



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DNA), comprising extracting mRNA (total mRNA) from tissues and cells and mRNA is hybridized with oligo-dT. After hybridization, cDNA is synthesized by Reverse Transcriptase (RT). The cDNA are reacted and immobilized so as to extend toward the terminal 5' of hybridized oligo-dT. Hybridized solution of synthesized immobilized cDNA and mRNA is heated in order to dehybridize mRNA (which would be the claimed replica of claim 22). A purified immobilized cDNA library in one chain DNA condition is prepared (see FIG. 7). In the case of gDNA library, immobilized oligonucleotides target restrictive enzymes (see. FIG. 8) are immobilized on surfaces of the diamond chips 41 as for oligo-dT. For chemical immobilization, the reaction solution is exchanged for reaction solution including hybridized oligonucleotides with target restrictive enzymes. After hybridization with oligonucleotides, the reaction solution is heated, so as to cut the restrictive enzymes of the semi-immobilized oligonucleotides. Therefore, the apparatus of Takahashi in which the method is performed would have inherently contained the feeding system. Silence in the prior art teaching does not mean that the prior art does not contain said feeding system. This is the more true since the system of Takahashi must contain said feeding system since the same method result is obtained, as that instantly claimed. As discussed above, the

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reaction conditions of Takahashi have been controlled as opposed to the instant claimed wherein the reaction conditions are given in general terms.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

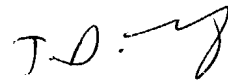
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

Tdw

March 20, 2004